IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF APPEALS

Appellant:	Thomas GOSTELOW	
Serial No:	10/643,939	
Filed:	August 20, 2003	
For:	MEDICO-SURGICAL INSTRUMENTS	Attorney Docket: 0119/0024

FEE AUTHORIZATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached herewith is an Appeal Brief relating to the above-identified application. The Commissioner is hereby authorized to charge the Appeal Brief fee of $500.00 using the attached form PTO-2038.

The Commissioner is further hereby authorized to debit funds from Deposit Account No. 50-0501 if the amount noted above is insufficient. A duplicate copy of this letter is attached.

Respectfully submitted,

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Date: May 16, 2007

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Appellant:	Thomas GOSTELOW	)	
Serial No:	10/643,939	)	Art Unit: 3771
Filed:	August 20, 2003	)	Examiner: Dixon, Annette F.
For:	MEDICO-SURGICAL INSTRUMENTS	)	Attorney Docket: 0119/0024

APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest of the subject application is Smiths Group PLC to which the inventor assigned his invention per an Assignment recorded August 20, 2003 on Reel 014411, Frame 0152 at the Assignment Branch of the U.S. Patent and Trademark Office.

RELATED APPEALS AND INTERFERENCES

An appeal for application No. 10/290,279 entitled "Medico-Surgical Apparatus" was filed on April 26, 2007. The '279 application also relates to the field of tracheostomy. However, it is believed that the outcome for the '279 application would not directly affect or be directly affected by, or have any bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1, 3-13 and 16-17 are pending in this application. Claims 2 and 14-15 were canceled.

Being appealed claims 1, 3-13 and 16-17, reproduced in the Claims Appendix, were finally rejected per an Office Action dated December 1, 2006.

STATUS OF AMENDMENTS

A Response, sans any amendment, was filed subsequent to the Office Action of December 1, 2006. In the Response, two articles were submitted to provide evidence of the inventiveness and the differences between the device of the claimed invention and the prior art.

SUMMARY OF THE CLAIMED SUBJECT MATTER

With reference to Figs. 1 and 2, claim 1 relates to a trachea ventilation medico-surgical instrument that comprises a hollow needle (1) having a sharp tip (12) adapted to penetrate the trachea through the neck tissue [page 5, lines 11-12]; an elongate inner member (13) located within the needle such that the member can slide along its length relative to the needle [page 5, lines 12-14]; a resilient member (18) adapted to urge the inner member forwardly relative to the needle, such that a forward end of the inner member is located forwardly of the needle tip before use but is displaced rearwardly during the passage through the neck tissue by engagement with the tissue and moves forwardly relative to the needle when the trachea is penetrated [page 15, line 17 to page 6, line 3]; a tracheostomy tube (3) removably supported by and extending along the outside of the needle [page 7, lines 4-6]; and an indicator (16) towards a rear end of the needle for indicating position of the elongate member relative to the needle such that the needle can be removed while the tracheostomy tube is left in position extending through the neck tissue, when the indicator indicates that the trachea has been penetrated [page 5, lines 14-17; page 7, lines 10-16].

Thus arranged, the medico-surgical instrument of the present invention, via its resilient member, causes the elongate member extending along the inside of the needle to be spring-loaded so that the indicator at the rear end of the needle would indicate to the user the position of the elongate member relative to the needle when the trachea of the patient is penetrated by the needle. As a consequence, a clear indication of the initial entry into the trachea, when the trachea has been penetrated, is obtained. This enables the user to have a high confidence in his ability to use the instrument correctly with a low risk of danger to the patient. The effectiveness of the claimed structure is evidenced by the two published articles attached to the Evidence Appendix which will be discussed *infra* in the Argument section.

Claim 13 relates to a tracheostomy instrument that includes an elongate inner member (13) located within a hollow needle (11) having a sharp tip (12) such that the member can slide along its length relative to the needle [page 5, lines 12-14]. The tracheostomy instrument further includes a spring (18) between the needle and the inner member urging the inner member forwardly relative to the needle such that a forward end

of the inner member is located forwardly of the needle tip before use but is displaced rearwardly during passage through the neck tissue by engagement with the tissue and moves forwardly relative to the needle when the trachea is penetrated [page 5, line 17 to page 6, line 2; page 7, lines 7-15]; a visual indicator (16, 17) towards the rear end of the needle for indicating the position of the elongate member relative to the needle so that the user knows that the trachea has been penetrated [page 5, lines 14-17; page 6, lines 13-18; page 7, lines 6-21]; and a dilator (2) mounted on the needle [page 6, lines 7-13]. The tracheostomy instrument moreover includes a tracheostomy tube (3) removably mounted on the dilator such that the patient end of the dilator extends beyond the patient end of the tracheostomy tube, and such that the dilator and the tracheostomy tube can be slid off the needle when the indicator indicates that the trachea has been penetrated [page 6, line 19 to page 7, line 2; page 8, lines 4-12].

The tracheostomy instrument of claim 13 therefore uses a spring between the needle and the inner member to urge the inner member forwardly relative to the needle such that the movement of the inner member relative to the needle would provide an indication, by means of the visual indicator, to the user as to whether the trachea of the patient has been penetrated.

Claim 16 relates to a method of inserting a tracheostomy tube (3) into a patient's trachea that comprises the steps of: loading the tracheostomy tube on an instrument that comprises a hollow needle (11) having a sharp tip (12), an elongate member (13) extending within the needle and projecting from the patient end of the needle, and an indicator (24) towards a machine end of the instrument for indicating the movement of the elongate member relative to the needle [page 5, line 10, page 7, line 7]. The method further includes the step of inserting a patient end of the instrument through the neck tissue of the patient into the trachea until a change in the status of the indicator indicates that the trachea has been penetrated [page 7, lines 7-16]. The method of claim 16 further comprises the step of sliding the instrument rearwardly relative to the tracheostomy tube to remove the instrument and to position the tracheostomy tube in the trachea [page 8, lines 1-12].

The method of claim 16 provides the clinician, by using the inventive instrument, a clear indication that the trachea has been entered without the need to use a syringe, as was done conventionally.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 16-17 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sauer (US 6,109,264).

B. Claims 1, 3, 5-11 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer in view of Fortune et al. (US 5,507,279).

C. Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer in view of Fortune et al. and Toye (US 6,382,209).

D. Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer in view of Fortune et al. and Yoon (US 5,423,760).

ARGUMENT

A. Anticipation rejection of claims 16 and 17 under Sauer (US 6,109,264)

"A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described in a single prior art reference." ... "The identical invention must be shown in as complete detail as contained in the ... claim." See MPEP 2131.

The method of claim 16 requires the loading of a tracheostomy tube on an instrument that includes an elongate member that extends within a hollow needle and projects from the patient end of the needle, and an indicator towards the machine end of the instrument that indicates the movement of the elongate member relative to the needle.

With such configuration, the user can determine, by means of the indicator, the movement of the elongate member, and therefore the movement of the tip of the needle towards and into the trachea. The instant inventive method therefore overcomes problems in the prior art that includes the risk that the insertion instrument is inserted either not far enough or too far into the trachea of the patient. To explain, if the clinician is too cautious he may not be able to make the insertion deep enough and this may prevent the correct positioning of the tracheostomy tube. On the other hand, if the clinician applies too much force in order to penetrate through the cartilage of the trachea, then he risks inserting the needle too deeply into the trachea to thereby possibly causing harm to the posterior wall of the trachea.

The inventive method further eliminates the problem that associates with the prior tracheostomy methods in that the prior methods require that separate devices, as well as separate insertion/removal steps, be involved/used before an adequate airway is provided. The complexity of having to use multiple devices and multiple insertion/removal steps cause delay, and possible harm to the patient, especially when performed by inexperienced medical personnel under stress in emergency situations.

As evidenced by the attached article "Evaluation of New Emergency Cricothyroidotomy Device in 10 Cadavers" by A Patel, the instant invention device, as used

per set forth in the at issue method claim 16, provides an easy one step penetration of the cricothyroid membrane, with the red indicator of the device confirming entry into the trachea and contact with the posterior cricoid wall, and that the device would be excellent for emergency cricothyroidotomy. Per the also attached article entitled "Evaluation of a New Cricothyroidotomy Kit Utilizing Built-In Veress Needle Trocar Technology" by Fernandez et al., the insertion of the inventive device is disclosed to require "no significant assembly and was performed in one rapid fluid motion facilitating ease of timely placement".

The examiner alleges that element 31 of Sauer is an elongate member and that element 24 is an indicator that indicates the movement of the elongate member 31 relative to a needle 41.

Appellant respectfully submits that the examiner has misconstrued Sauer, for Sauer does not come close to disclosing, or suggesting, the instrument required in the method of claim 16, per the following.

As shown in Fig. 4, the Sauer device includes an inner tube 15 having its proximal end attached to a retraction housing 54. As amplified by the exploded view of Fig. 7, a needle driver 138, biased by a spring 136, is enclosed by inner tube 15. Spring 136 is fitted to needle bushing 134, as shown in Fig. 9. An aspirator fitting 150, also shown in Fig. 9, is mounted to the bottom of needle bushing 134. The assembled partially cut-away perspective view of the inner tube 15, the needle driver 138, the needle bushing 134, and as those elements are retained in the retraction housing 54, is shown in Fig. 10. As best shown in the cross sectional views of Figs. 14-17, the guidewire 31 is mounted to a thumb ring 29 and extends within needle 41. Note that the aspirator fitting 150 (as best shown in Fig. 15) does not come into contact with guidewire 31, and in fact has nothing to do with guidewire 31, as it in essence is a conduit that allows the air flowing within the needle 41, through which guidewire 31 is also positioned, to be routed to aspirator bulb 24 (column 8, lines 20-26).

Spring 136 is a part of needle retraction assembly. One end of the spring 136 is engaged to flange 135 of the needle bushing 134 (Figs. 7-9) while its other end is engaged to elongate member 14 (Fig. 3; column 7, lines 47-51). The needle bushing 134 is

connected to a needle latch 140, which in turn is coupled to the thumb ring 29, so that when thumb ring 29 is pushed inwards toward the handle of the Sauer device, trigger 154 (Fig. 7) will cause the spring 136 to expand from its compressed state to retract needle driver 138 and therefore also needle 41 within the dilator tip 68 of the foldable dilator 30 (Fig. 27).

With reference to Figs. 19-24, to operate the Sauer device, the aspiration bulb 24 is first depressed so that when needle 41 has penetrated into the trachea, the pressurized air due to the aspirator bulb 24 having been depressed (Fig. 21) is communicated to the trachea through the aspiration passageway 205, so that the aspirator bulb is rapidly re-inflated (Fig. 22, column 10, lines 17-27). It is only after confirmation that needle 41 has penetrated the tracheal wall would guidewire 31 be manipulated, by means of thumb ring 29 into the trachea, per shown in Fig. 22 (column 10, lines 32-37). Subsequent to the proper positioning of the so far deflated dilator 30 within the trachea (Fig. 28) and after retraction of needle 41 (Fig. 27), the dilator 30 is inflated (Fig. 29) to dilate the tracheal rings, by means of fluid input into the dilator from pump assembly 72 (Figs. 14 and 31). The further insertion of the tracheostomy tube into the patient is shown in Fig. 32 and the retraction of the Sauer apparatus from the tracheostomy tube is shown in Fig. 33.

Per the above explanation, it should be apparent that Suer does not disclose any elongate member that extends within the needle and projects through the patient's end or any indicator that indicates the movement of the elongate member relative to the needle. There simply is no such elongate member or indicator disclosed or suggested in Sauer, for the Sauer guidewire 31 has no association with the aspirator bulb 34, as guidewire 31 is positioned inside needle 41 during the time that needle 41 is used to puncture the trachea of the patient. During that time, guidewire 31 is not being moved or is moveable. Further as explained above, it is the air that is under pressure by the pressing of the aspirator bulb that, when needle 41 punctures the trachea of the patient, escapes into the trachea to thereby enable aspirator bulb 34 to once again be re-inflated that provides the indication to the user that the trachea wall has been punctured by the Sauer device. Accordingly, not only are the elements required for the tracheostomy tube of the method claim 16 missing from Sauer, the construction as well as the function of the Sauer device are totally different from those of the inventive device being used in the method of claim 16.

In light of the above, Appellant respectfully submits that the anticipation rejection of claim 16, and claim 17 dependent therefrom, under Sauer is not sustainable.

B. Obviousness rejection of claims 1, 3, 5-11 and 13 under the combination of Sauer (US 6,109,624) and Fortune (US 5,507,279)

For this rejection, after alleging that Sauer discloses all of the elements as noted in the anticipation rejection, the examiner admitted that "Sauer does not expressly disclose the limitations of the elongated inner member in cooperation with the resilient member." See page 4 of Office Action. The examiner then alleges that Fortune shows such relationship.

In *KSR International Co. v Teleflex Inc.*, (No. 04-1350, decided April 30, 2007), the Supreme Court held that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." At page 12 of slip opinion. The Court further held that "it will be necessary ... to look to interrelated teachings of multiple patents; the effects of demands known in the design community or present in the market place; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *Ibid.* at page 14.

As discussed above in the Summary of the Claimed Subject Matter section, claims 1 and 13 each are related to an instrument for effecting tracheostomy. Claim 1 particularly requires "a resilient member adapted to urge the inner member forwardly relative to the needle such that a forward end of inner member is located forwardly of the needle tip before use but is displaced rearwardly during passage through the neck tissue by engagement with the tissue and moves forwardly relative to the needle when said trachea is penetrated" and "an indicator towards a rear end of the needle for indicating position of the elongate member relative to said needle such that said needle can be removed to leave the tracheostomy tube in position extending through the neck tissue when said indicator indicates that the trachea has been penetrated".

In place of a resilient member, claim 13 calls for "a spring between said needle and said inner member urging said inner member forwardly relative to said needle" and also "a visual indicator" towards a rear end of the needle that indicates the movement of the elongate member relative to the needle, in order to inform the user that the trachea has been penetrated by the needle.

As discussed above in section A, Sauer fails to disclose or teach any elongate member or indicator that has the kind of interrelationship as required in each of claims 1 and 13.

Fortune (US 5,507,279) discloses a kit and a technique to use the components in the kit for retrograde insertion of an endotracheal tube. The technique taught by Fortune in particular uses a trachea puncture device 12 that first makes a hole in the trachea of the patient. A guidewire is next fed from the trachea of the patient out through the mouth of the patient. The guidewire is then used to guide an endotracheal tube into the trachea of the patient via the patient's mouth. The steps for preforming this technique are shown in Figs. 9-12 of Fortune.

As for the examiner's assertion that Fortune fills the admitted gap in Sauer that Sauer does not expressly disclose the limitations of the elongated inner member in cooperation with the resilient member (or spring), Appellant respectfully submits that Fortune does no such thing. To wit, the hollow stem 24 that is movable within needle 22 in the Fortune device does not function in the same way as the inner member's movement relative to the needle as required in each of independent claims 1 and 13. This is apparent in that Figs. 1 and 2 of Fortune which show stem 24 being connected to a first stop member 52, which in turn is connected to a second stop member 54 by a detent 50. As disclosed in column 5, lines 1-54, the lever actuated locking mechanism 40 is used to control how far the blunt end 28 of stem 24 is biased by spring 38 from needle point 30 of needle 22. As best shown in Fig. 1, so long as the first stop member 52 is biased against the cantilever arm 46 of the locking mechanism 40, stem 24 is allowed to be moved by the neck tissue of the patient as needle 22 is inserted to the patient. However, once the needle extends into the trachea, due to the force acting upon the second stop member 54 by spring 38, the blunt end of stem 24 would extend beyond the needle point 30 of needle 22, and remains fixed at that position due to cantilever arm 46 locking onto detent 50 to

prevent further movement of stem 24 relative to needle 22. The tracheal puncture device 12 is then left in place while a guidewire carrier 62 is attached to it so that the guidewire 18 could be fed into the aperture 60 through stem 24 and out through the mouth of the patient (Fig. 3). The guidewire is then used as a guide for the insertion of an endotracheal tube into the patient via the mouth of the patient (Figs. 11 and 12).

Given the respective constructions of the Sauer and Fortune devices, it is apparent that a person having ordinary skill in the art would not have combined Fortune with Sauer per asserted by the examiner insofar as the Sauer aspiration bulb 24 could not be moved or be affected by the movement of the Fortune stem 24, which is fixed after a given movement per discussed above. Putting it differently, the combination of Sauer and Fortune fails to provide an indicator that moves in conjunction with an elongate member. Indeed, neither Sauer nor Fortune discloses, or suggests, an indicator that indicates the position of an elongate member relative to a needle as required in claims 1 and 13. Thus, the obviousness rejection under Sauer and Fortune never reaches the threshold mandated by the KSR court, as elements not familiar to those required in the present invention are being relied upon by the examiner in her rejection. And with no familiar elements, there could not be any predictable results.

In light of the foregoing, Appellant respectfully submits that the rejection of claims 1 and 13 as being unpatentable over the combination of Sauer and Fortune is not sustainable.

Inasmuch as claims 3 and 5-11 each depend, either directly or indirectly from claim 1, those claims likewise are believed to be patentable over the combination of Sauer and Fortune. That notwithstanding, Appellant respectfully submits that claims 8, 9 and 10 each are separately patentable over the combination of Sauer and Fortune per the following.

In particular, neither Sauer nor Fortune discloses or suggests any of the following features: an inner member that is closed at its patient end and opens through a side opening adjacent to the patient end, as required in claim 7; an inner member that opens through two side openings adjacent to the patient end, as required in claim 8; or a coupling (119) towards a machine end of the inner member by which gas can be supplied to the inner member (page 9, lines 13-14; Fig. 3), as required by claim 10.

C. Obviousness rejection of claim 4 under the combination of Sauer, Fortune and Toye (US 6,382,209)

Inasmuch as claim 4 incorporates by reference the limitations of claim 1 and insofar as it is believed that claim 1 is patentable over the prior art, it is respectfully submitted that claim 4 likewise is patentable over the combination of Sauer, Fortune and Toye.

D. Obviousness rejection of claim 12 under the combination of Sauer, Fortune and Yoon (US 5,423,760)

Claim 12 defines the visual indicator to be a colored flag (16, 17) movable behind a transparent window [page 7, lines 6-15].

Yoon does not disclose or suggest such, for Yoon merely discloses that his housing body is made of a transparent material and a floating ball 100 is disposed in the chamber 94 (column 8, lines 34-38). Alternatively, Yoon discloses that the proximal end of the needle can be made a first, predetermined color and the tube 50 can be made a second, different predetermined color (column 9, lines 8-20). Notwithstanding that claim 12 depends indirectly from claim 1 and therefore by that alone claim 12 should be deemed not obvious over the prior art as discussed above, it is further respectfully submitted that a transparent window is not the same and could not be deemed to be obvious in light of the device housing, and that a specifically defined colored flag movable behind the transparent window likewise is not the same and could not be deemed to be obvious in light of the floating ball or the end of a needle as taught in Yoon.

Summary

For the reasons discussed above, Appellant respectfully submits that all of the pending claims in the present application are patentably distinguishable over the cited references. Accordingly, the Board is respectfully requested to reverse the examiner's rejections.

Respectfully submitted,

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CLAIMS APPENDIX

1. A medico-surgical instrument for ventilation via the trachea comprising: a hollow needle having a sharp tip adapted to penetrate the trachea through neck tissue; an elongate inner member located within said needle such that the member can slide along its length relative to the needle; a resilient member adapted to urge said inner member forwardly relative to said needle, such that a forward end of said inner member is located forwardly of said needle tip before use but is displaced rearwardly during passage through neck tissue by engagement with the tissue and moves forwardly relative to said needle when said trachea is penetrated; a tracheostomy tube removably supported by and extending along the outside of said needle; and an indicator towards a rear end of said needle for indicating position of said elongate member relative to said needle such that said needle can be removed to leave the tracheostomy tube in position extending through neck tissue when said indicator indicates that the trachea has been penetrated.

2. (Canceled)

3. An instrument according to Claim 1 including a dilator with a tapered patient end mounted on said needle, and wherein said tracheostomy tube is mounted on an outside of the dilator with the tapered end of the dilator projecting from a patient end of said tracheostomy tube.

4. An instrument according to Claim 1, wherein said tracheostomy tube is helically reinforced.

5. An instrument according to Claim 1, wherein said tracheostomy tube is cuffed.

6. An instrument according to Claim 1, wherein said inner member is hollow and provides a gas passage along said member.

7. An instrument according to Claim 6, wherein said inner member is closed at its patient end and opens through a side opening adjacent the patient end.

8. An instrument according to Claim 7, wherein said inner member opens through two side openings adjacent the patient end.

9. An instrument according to Claim 7, wherein said side opening is longitudinally elongated.

10. An instrument according to Claim 6 including a coupling towards a machine end of said inner member by which gas can be supplied to said inner member.

11. An instrument according to Claim 1, wherein said indicator means includes a visual indicator.

12. An instrument according to Claim 11, wherein said visual indicator includes a colored flag movable behind a transparent window.

13. A tracheostomy instrument for ventilation via the trachea comprising: a hollow needle having a sharp tip adapted to penetrate the trachea through neck tissue; an elongate inner member located within said needle such that the member can slide along its length relative to the needle; a spring between said needle and said inner member urging said inner member forwardly relative to said needle, such that a forward end of said inner member is located forwardly of said needle tip before use but is displaced rearwardly during passage through neck tissue by engagement with the tissue and moves forwardly relative to said needle when said trachea is penetrated; a visual indicator towards a rear end of said needle for indicating position of said elongate member relative to said needle so that the user knows that the trachea has been penetrated; a dilator mounted on said needle; and a tracheostomy tube removably mounted on said dilator such that a patient end of said dilator extends beyond a patient end of said tracheostomy tube and such that said dilator and tracheostomy tube can be slid off said needle when said indicator indicates that the trachea has been penetrated.

14-15. (Canceled)

16. A method of inserting a tracheostomy tube into a patient's trachea comprising the steps of: providing said tracheostomy tube loaded on an instrument comprising a hollow needle having a sharp tip, an elongate member extending within the needle and projecting from a patient end of said needle and an indicator towards a machine end of the instrument for indicating movement of said elongate member relative to said needle;

inserting a patient end of the instrument through neck tissue of a patient into the trachea until a change in the status of the indicator indicates that the trachea has been penetrated; and sliding said instrument rearwardly relative to said tracheostomy tube to remove said instrument and to position said tracheostomy tube in the trachea.

17. A method according to Claim 16, wherein said tracheostomy tube is loaded on a dilator on said instrument and the method includes the step of advancing said dilator forwardly along said instrument to advance said tracheostomy tube into the trachea, and subsequently removing said dilator to leave said tracheostomy tube in position.

Difficult Airway Society Annual Scientific Meeting 25-26 November 2004

Evaluation of a New Emergency Cricothyroidotomy Device in 10 Cadavers

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Introduction

A new Emergency Cricothyroidotomy Device (Smiths Medical,UK) has been developed in conjunction with the UK Military Special Forces for emergency airway access in the field. The device allows a single step introduction of a 6mm I.D. cuffed, 90mm long cricothyroidotomy tube over an integral obturator/dilator and allows spontaneous and mechanical ventilation. Confirmation of both entry into the trachea through the cricothyroid membrane and safety during insertion is achieved by the use of a Veress needle with a blunt, spring loaded, stylet which protrudes beyond the sharp needle tip, preventing trauma to the posterior tracheal wall. The stylet is pushed back to expose the cutting edge of the needle during insertion through tissues. A red indicator is clearly visible in the Veress needle hub on insertion but disappears once the needle tip has correctly entered the trachea.
This study aimed to assess the performance of the device, ease of insertion, confirmation of Veress needle red indicator use, time for insertion and assessment of posterior tracheal wall trauma.

Method

The study was undertaken at the Medical Education & Research Institute, Memphis, USA. All cadavers were donated to the institute with donor signed consent forms.
Each cadaver had a flexible fibre-optic bronchoscope placed at the level of the vocal cords to observe for posterior tracheal wall trauma. Time from skin incision to tube flange placement at the neck was recorded. Identification of anatomical landmarks, location of cricothyroid membrane, insertion force and overall assessment of the procedure was documented. A 5.3mm catheter and a fibre-optic bronchoscope were passed down the internal lumen of each tube to confirm patency and no kinking of the tube. Following cricothyroidotomy tube removal the trachea was examined for signs of posterior tracheal wall injury down to the carina.

Results

The Emergency Cricothyroidotomy Device was successfully inserted in all 10 cadavers. Mean (range) Age; years 74.8 (55-89), Weight; Kg 77 (43-120), Height; m 1.75 (1.58-1.93), Time to insertion; seconds 49 (30-89)

Identification of anatomical landmarks	Easy	6	Moderate	3	Difficult	1
Location of cricothyroid membrane	Superficial	6	Intermediate	4	Deep	0
Insertion Force	Easy	3	Moderate	7	Difficult	0
Overall Assessment	Easy	9	Moderate	0	Difficult	1

In all 10 cadavers the cricothyroid membrane was penetrated easily, the red indicator confirmed entry into the trachea and contact with the posterior cricoid wall. The device was easy to hold, direct, and angle caudally. In all cadavers the tube slid off the obturator easily, the obturator was easy to remove and the flange of the device located on the neck satisfactorily.
The passage of a catheter and fibre-optic bronchoscope confirmed tube patency and no kinking in all tubes.
For the first two cadavers minor/acceptable and major/acceptable trauma occurred to the posterior cricoid cartilage. In both of these insertions the investigator was observing the video monitor and not the red indicator in the needle hub showing the posterior cricoid cartilage had been reached. Similarly for the first and third insertion contact was made with the posterior tracheal wall (red indicator). None of the cadavers showed any trauma to the posterior tracheal wall.

Discussion

The overall assessment of the device showed easy insertion in 9 cadavers and a difficult insertion in 1 due to difficult identification of anatomical landmarks. The device is quick and easy to insert with a mean insertion time of 49 seconds.
The only problems arose in the first 3 cadavers with trauma to the cricoid cartilage and contact with the posterior tracheal wall although no damage to the posterior tracheal wall was identified. This may represent a short (2-3 insertions) learning curve as the subsequent 7 cases were uneventful.

Conclusion

The Emergency Cricothyroidotomy Device was successfully inserted in all 10 cadavers and would be an excellent device for use when an emergency cricothyroidotomy is indicated. An airway was achieved in less than 1 minute with no trauma to the posterior tracheal wall. A short learning curve (2-3 insertions) appears to exist.

Evaluation of a New Cricothyoidotomy Kit Utilizing Built-in Veress Needle Trocar Technology

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Introduction:

One option toward securing the airway in a "cannot ventilate/cannot intubate" situation, when other modalities have failed, is to obtain surgical access to the airway. A new cricothyroidotomy kit (Portex Emergency Cricothyroidotomy Kit, Smiths Medical, Hythe, UK) utilizes Veress needle technology to facilitate introduction of the dilator and endotracheal tube through the cricothyroid membrane in a single maneuver. This product is designed with a built in "red flag indicator" which retracts upon penetration of the cricothyroid membrane indicating intra-tracheal position and reappears if the blunt portion of the Veress needle tip comes into contact with the opposing tracheal wall, potentially minimizing the chance of injury to the vulnerable soft posterior membranous trachea. The safety and effectiveness of this new needle/dilator design is the subject of this study.

Methods:

Experienced airway managers with anesthesia, emergency medicine and trauma surgery backgrounds were provided instruction with the preassembled kit via a DVD based video demonstration followed by insertion practice on a manikin specifically designed for performing surgical airway access via the cricothyroid membrane. Following this training, the operators then performed insertion of the surgical airway (6.0mm, I.D.) into partially thawed (non-fresh) cadavers. Pathologic evaluation of the hyoid-cricotracheal complex was performed following the procedure, assessing for airway position and the presence or absence of associated injury. Successful airway insertions were defined as central intralumenal positioning of the device in the airway with a patent distal tip. Successful insertions were further classified as non-injurious and injurious depending on presence or absence of associated tracheal or paratracheal injury.

Results:

33/40 (83%) had successful insertion of the PCK airway. Of these 33 successful insertions, 24/33 (73%) were non-injurious (19 no complication, 3 abrasions ≤1.5cm, 2 abrasions ≥1.6cm). 9/33 (27%) were injurious (4 lacerations ≤1.5cm, lacerations, 3 lacerations ≥1.6cm, one first tracheal ring injury*, and one thyroid

cartilage fracture**). Seven cases of insertion failure were observed. 4 of 7 cases correctly passed through the cricothyroid membrane but resulted in a misplaced distal tip of the endotracheal tube penetrating the opposite wall of the trachea (3 posterior, 1 lateral). 3 of the 7 insertion failures never penetrated the cricothyroid membrane and were entirely extra-tracheal (2 paratracheal, 1 subcutaneous, 1 ineffective penetration of tissues***). Timeliness of insertion was quantified by reviewing video footage of the procedures and timing from the time the knife was grasped for making the skin incision to the beginning of the first ventilation following insertion. Insertion times ranged from 20 -122 seconds with a mean insertion time of 42.3 seconds.

* Introduction resulted in a thyroid cartilage fracture. Poor external landmark definition reported by practitioner.
** Airway inadvertently placed via the cricotracheal membrane lead to fracture of the 1st tracheal ring. Poor external landmark definition reported by practitioner.
***Marked deformity of cadaver and postmortem lividity made penetration of tissues impossible. Procedure aborted.

Conclusion:

The PCK airway system allowed rapid and expeditious placement of an endotracheal surgical airway in the majority of insertions (83%). This success rate is comparable or better than other previous reports utilizing pathologic analysis for confirmation of tube placement and identification of associated injury in surgical crycothyroidotomy[1, 2]. Insertion required no significant assembly and was performed in one rapid fluid motion facilitating ease of timely placement. However, despite its innovative design, injuries and potentially disastrous airway placement difficulties were not completely avoided. Further study of this system in a live animal model may provide a more realistic and accurate appraisal of PCK airway's performance in the clinical setting and appears indicated prior to any widespread application or abandonment of this new and innovative technology.

References:

[1]Schaumann N et al., Evaluation of Seldinger Technique Emergency Cricothyroidotomy versus Standard Surgical Cricothyroidotomy in 200 Cadavers. Anesthesiology, Jan 2005; 102(1):7-11.

[2]Eisenburger P, Comparison of conventional surgical versus Seldinger technique emergency cricothyroidotomy performed by inexperienced clinicians. Anesthesiology, Mar 2000; 92(3):687-90.

RELATED PROCEEDINGS APPENDIX

None.